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ATTY DOCKET 53951-055Amendments to Claims

1-2. (Canceled)

3. (Previously Amended) A method as in claim 1, A method of detecting leaks in an extracorporeal blood circuit, comprising the steps of:

detecting liquid outside a normally dry environment of a first portion of a blood circuit;

detecting air inside a second portion of a blood circuit located remote from said first portion such that fluid is not detectable from said second portion;

generating an alarm signal responsively to a result of either or both of said steps of detecting;

wherein said second step of detecting includes applying a positive gauge pressure to said circuit during a first time and applying a negative pressure to said blood circuit during a second time.

4. (Canceled)

5. (Previously Amended) A method of detecting leaks in an extracorporeal blood circuit, comprising the steps of:

detecting fluid outside a first portion of a blood circuit;

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detecting air inside a second portion of a blood circuit located remote from said first portion such that fluid is not detectable from said second portion;
generating an alarm signal responsively to a result of either or both of said steps of detecting; A method as in claim 1, wherein said second step of detecting includes periodically reversing a flow in said blood circuit.

6-11. (Canceled)

12. (Previously Amended) A leak detection system for an extracorporeal blood circuit, comprising:

a fluid detector located in a position to capture leaking blood from a first portion of said blood circuit;
a mechanism in said blood circuit to, at least periodically, create a negative pressure in all portions of a patient side of said blood circuit such that any leaks in said all portions will result in infiltration of air;

an air infiltration detector located to detect air infiltrating said all portions;

an alarm connected to both said air infiltration detector and said fluid detector and configured to generate an alarm signal if either said air infiltration detector or said fluid detector indicates a leak; A device as in claim 10,

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wherein said mechanism includes a device adapted to reverse flow direction in said blood circuit.

13. (Original) A device as in claim 12, wherein said device adapted to reverse flow includes a reversing valve.

14. (Previously Amended) A device as in claim 13, further comprising a funnel-shaped container positioned with respect to said fluid detector to guide any blood leaking from said blood circuit toward said fluid detector located at a bottom of said container.

15. (Currently Amended) A device as in claim [[14]] 12, further comprising a funnel-shaped container positioned with respect to said fluid detector to guide any blood leaking from said blood circuit toward said fluid detector located at a bottom of said container wherein said funnel-shaped container is built into a housing of a blood processing machine of which said blood circuit is a part.

16. (Canceled)

17. (Previously Amended) A device for detecting leaks in a blood circuit, comprising:

a first leak detector that detects leaks by sensing any presence of blood outside said blood circuit, said first leak detector being located to detect leaks from a first portion of said blood circuit located remote from a patient;

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a second leak detector that detects leaks by sensing air infiltration into lines under negative pressure;

said second leak detector being configured to detect leaks in lines connecting said patient to said first portion;

a mechanism that insures that at least part of said lines are under negative pressure at least part of the time during a treatment such that a detectable air infiltration indicates a presence of a leak in said lines;

an alarm device that outputs an alarm signal responsively to a detection of a leak by said first or second leak detector.

18. (Previously Amended) A device as in claim 17, wherein said second leak detector includes a liquid fluid sensor below said circuit first portion.

19. (Previously Amended) A device as in claim 17, wherein said mechanism includes a flow-reversing valve in said blood circuit effective to reverse flow direction in said lines.

20. (Previously Amended) A device as in claim 17, where in said first leak detector is located below said first portion, said device further comprising a flow director to concentrate any leaking fluid toward said first leak detector.

21-24. (Canceled)

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25. (Previously Amended) ~~A method as in claim 25, A~~
method of detecting a fluid leak from a fluid processing
machine, comprising the steps of:

detecting infiltration of air into a fluid circuit;
detecting leakage of fluid from said fluid circuit;
generating a response including an alarm responsive
to said first and second steps of detecting;

wherein said step of generating includes reversing a
flow direction of fluid.

26-37. (Canceled)

38. (Previously Amended) ~~A method as in claim 28, A~~
method of detecting a leak from a blood circuit of an
extracorporeal blood treatment machine, comprising the steps of:

detecting leakage of blood from respective portions of
a blood circuit;

said step of detecting including detecting different
physical effects resulting from respective conditions associated
with one or more leaks;

said respective portions including parts that are non-
overlapping;

wherein said different physical effects include the
infiltration of air into a blood circuit by periodically

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generating a negative pressure in said blood circuit and the presence of blood outside said blood circuit.

39. (Previously Amended) A method as in claim 38, wherein said step of generating includes reversing a flow direction of blood.

40. (Previously Amended) ~~A method as in claim 28, A~~ method of detecting a leak from a blood circuit of an extracorporeal blood treatment machine, comprising the steps of: detecting leakage of blood from respective portions of a blood circuit;

said step of detecting including detecting different physical effects resulting from respective conditions associated with one or more leaks;

said respective portions including parts that are non-overlapping;

wherein said different physical effects include the any air bubbles or infiltration of air into a blood circuit by periodically reversing a flow direction of blood in said blood circuit using a reversing valve and the presence of any blood outside said blood circuit.

41. (Canceled) .

42. (Previously Amended) A method as in claim 40, wherein said presence is detected by guiding and concentrating a

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leaking flow of blood toward a blood, plasma, or liquid sensitive fluid sensor.

43-46. (Canceled)

47. (Previously Amended) A device as in claim 46, A device for detecting a fluid leak from a fluid processing machine, comprising the steps of:

an air detection sensor located to detect infiltration of air into a fluid circuit of said fluid processing machine;

a fluid detector located to detect a leakage of fluid from said fluid circuit;

an alarm connected to said sensor and said fluid detector and configured to output an alarm signal responsive to signals therefrom;

a mechanism adapted to generate a negative pressure in said fluid circuit to cause air to infiltrate into a breach in said fluid circuit;

wherein said mechanism is adapted to reverse a direction of flow of fluid in said fluid circuit.

48-59. (Canceled)

60. (Previously Amended) A device as in claim 59, A device for detecting a leak from a blood circuit of an extracorporeal blood treatment machine, comprising the steps of:

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respective detectors located to detect leaks of blood
from respective portions of a blood circuit;

at least two of said respective detectors including
sensors configured to detect different physical effects
correlated with one or more blood leaks;
said respective portions including parts that are non-
overlapping;

wherein said different physical effects include the
infiltration of air into a blood circuit and the presence of
blood outside said blood circuit;

an output device connected to receive signals from said
respective detectors and to output a signal responsive thereto
and an alarm connected to generate an output responsive to
said signal;

wherein said output device and detectors are configured
such that said signal indicates a leak if either of said
respective different physical effects indicates a leak;

wherein at least one of said detectors includes an air
sensor or bubble sensor and a mechanism adapted to periodically
generate a negative pressure in said blood circuit such that air
infiltrates said blood circuit through any openings therein.

61. (Original) A device as in claim 60, wherein said
mechanism includes a mechanism adapted to reverse flow.

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62. (Previously Amended) A device as in claim 50, A device for detecting a leak from a blood circuit of an extracorporeal blood treatment machine, comprising the steps of: respective detectors located to detect leaks of blood from respective portions of a blood circuit; at least two of said respective detectors including sensors configured to detect different physical effects correlated with one or more blood leaks; said respective portions including parts that are non-overlapping; further comprising a reversing valve, said different physical effects include the infiltration of any air into said blood circuit caused by periodically reversing a flow of blood in said blood circuit using said reversing valve.

63. (Currently Amended) A device as in claim 62, A device for detecting a leak from a blood circuit of an extracorporeal blood treatment machine, comprising the steps of: respective detectors located to detect leaks of blood from respective portions of a blood circuit; at least two of said respective detectors including sensors configured to detect different physical effects correlated with one or more blood leaks;

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said respective portions including parts that are non-overlapping;

a flow reversing pump;

said different physical effects include the infiltration of any air into said blood circuit caused by periodically reversing a flow of blood in said blood circuit using said reversing pump;

wherein said detectors include a fluid sensor located inside a housing of said extracorporeal blood treatment machine.

64. (Original) A device as in claim 63, further comprising a flow guide adapted to guide and concentrate a leaking flow of blood toward said fluid sensor.

65. (Previously Submitted) A method for detecting leaks in an extracorporeal blood circuit, comprising:

detecting blood or liquid outside a normally dry first portion of a blood circuit;

detecting air inside a second portion of the blood circuit that is remote from the first portion;

said step of detecting air including periodically reversing a flow in said blood circuit; and

generating an alarm signal signifying the occurrence of either or both types of fluid leakage detections in said steps of detecting.

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66. (Previously Submitted) A method for detecting leaks in an extracorporeal blood circuit, comprising:
detecting blood or liquid outside a first portion of a blood circuit;
detecting air inside a second portion of the blood circuit that is remote from the first portion;
said step of detecting air including causing infiltration of air into the blood circuit by periodically generating a negative pressure in said blood circuit; and generating an alarm signal signifying the occurrence of either or both types of fluid leakage detections in said steps of detecting.

67. (Previously Submitted) A method as in claim 66, wherein said step of causing includes reversing a flow of blood in said blood circuit.

68. (Currently Amended) A method as in claim 66, wherein said step of detecting blood or liquid includes providing a liquid sensor within a housing of a blood treatment machine.

69. (Previously Submitted) A device for detecting leaks in an extracorporeal blood circuit, comprising:
a liquid detector positioned to detect blood or liquid outside a first portion of a blood circuit;

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an air detector positioned to detect air inside a second portion of the blood circuit that is remote from the first portion;

a flow reverser configured to periodically reverse a flow in said blood circuit such that air is caused to be infiltrated in portions that are otherwise not under negative pressure; and

an alarm configured to signify the occurrence of a leak in response to either or both of said liquid detector and said air detector.

70. (Previously Submitted) A device for detecting leaks in an extracorporeal blood circuit, comprising:

a liquid detector positioned to detect blood or liquid outside a first portion of a blood circuit;

an air detector positioned to detect air inside a second portion of the blood circuit that is remote from the first portion;

a positive displacement mechanism configured to periodically generate a negative pressure in said blood circuit such that air is caused to be infiltrated in portions that are otherwise not under negative pressure; and

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an alarm configured to signify the occurrence of a leak in response to either or both of said liquid detector and said air detector.

71. (Previously Submitted) A device as in claim 70, wherein said positive displacement mechanism includes a reversible pump in said blood circuit.

72. (Previously Submitted) A device as in claim 70, wherein said liquid detector is positioned within a housing that houses said blood circuit first portion.

73. (Previously Submitted) A device as in claim 72, wherein said housing includes a funnel shaped portion to guide leaking blood to said liquid detector.

74. (Previously Submitted) A method for detecting leaks in a blood treatment machine, comprising the steps of: during a treatment operation, detecting liquid outside a blood circuit, at least a first portion of which is under non-negative pressure during a treatment operation;

creating a temporary negative pressure at least two times during said treatment operation in at least a second portion of said blood circuit effective to cause air to infiltrate said second portion;

detecting said air caused to infiltrate by said step of creating;

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at least one of halting a pumping of blood in either or both of said first and second blood circuit portions or generating an alarm signal responsively to a result of either or both of said steps of detecting.

75. (Previously Submitted) A method for detecting leaks in a blood treatment machine, comprising the steps of: during a treatment operation, detecting liquid outside of a first portion of a blood circuit that is under non-negative pressure, the outside being normally dry; detecting air inside a second portion of a blood circuit by reversing blood flow at least two times during said treatment operation in said second portion effective to cause air to infiltrate said second portion; halting a pumping of blood in either or both of said first and second blood circuit portions responsively to a result of either or both of said steps of detecting.

76. (Previously Submitted) A method for detecting leaks in a blood treatment machine, comprising the steps of: during a treatment operation, detecting liquid outside a first portion of a blood circuit that is under non-negative pressure; detecting air inside a second portion of a blood circuit by creating a temporary negative pressure at least two

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times during said treatment operation in said second portion effective to cause air to infiltrate said second portion; generating an alarm signal responsively to a result of either or both of said steps of detecting.

77. (Canceled).

78. (Previously Submitted) A device for detecting leaks in an extracorporeal blood circuit, comprising:
a liquid detector configured to detect leaks in a blood circuit by detecting blood or liquid outside a first portion of a blood circuit, the first portion being remote from a patient;
an air detector configured to detect air leaks into the blood circuit by sensing any air infiltration into blood circuit lines connecting the patient to the first portion;

a mechanism configured to ensure a negative pressure, at least part of the time during a treatment operation, said blood circuit lines connecting said patient;

an alarm device configured to output an alarm signal to signify the occurrence of a leak responsively to either or both of said liquid detector and said air detector.

79. (Previously Submitted) A device for detecting leaks in a blood treatment machine, comprising:

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a liquid detector configured to detect liquid outside a first portion of a blood circuit that is under non-negative pressure during a treatment;

a positive displacement device configured to generate a temporary negative pressure at least two times during said treatment operation in a second portion effective to cause air to infiltrate said second portion, where said second portion is ordinarily under non-negative pressure during said treatment;

an air detector configured to detect air infiltrated into said second portion at least during said at least two times;

a controller to one of halt a pumping of blood or generate an alarm signal in response to a detection by either of said liquid detector and said air detector.

80. (Previously Submitted) A device for detecting leaks in a blood treatment machine, comprising:

a blood pump engageable with blood line configured to connect a patient access to a treatment mechanism;

an air detector configured to detect air in said blood line;

a flow reversing device between said blood pump and an end thereof configured to connect to said patient access, said flow reversing device being configured to reverse a flow of

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blood in said blood line and to cause air infiltration as a result of negative pressure in at least a portion of said blood line due to said negative pressure to be transported to be detected by said air detector;

a liquid detector positioned to detect liquid outside a portion of said blood line between said blood pump and said treatment mechanism such that blood leaking out of said portion is detected thereby;

a controller to one of halt a pumping of blood by said blood pump or generate an alarm signal in response to a detection by either of said liquid detector and said air detector.

81. (Previously Submitted) A device for detecting leaks in a blood treatment circuit, comprising:

a first leak detector that detects leaks by sensing liquid in an otherwise dry outside environment of said blood treatment circuit, said first leak detector being located to detect leaks from at least a first portion of said blood treatment circuit;

a second leak detector that detects leaks by sensing air or bubble infiltration into lines of said blood treatment circuit under negative pressure;

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said second leak detector being configured to detect leaks at least in said lines of said blood treatment circuit that connect said patient to said first portion;

a positive displacement mechanism that insures that at least part of said lines are under negative pressure at least part of the time during a treatment such that a detectable air or bubble infiltration indicates a presence of a leak in said lines;

an alarm device that monitors said first and second leak detectors during a treatment and generates a response signal responsively to a detection of a leak by said first or second leak detector.

82. (Previously Submitted) A device as in claim 81, wherein said alarm device includes an audio alarm signal generator.

83. (Previously Submitted) A device as in claim 81, wherein said positive displacement mechanism includes a pump with a reversible flow direction.